AMERICAN DIAGNOSTIC CORPORATION

NOV 0 1 2001

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K012304 .

1. **Submitter's Identification:**

Mr. Marc Blitstein
President
American Diagnostic Corporation
55 Commerce Drive
Hauppauge, NY 11788

Date Summary Prepared: April 16, 2001

2. **Name of the Device:**

ADC 656 Electronic Stethoscope……

CV 2.0

SF 27

55 Commerce Drive
Hauppauge, NY 11788
Customer Service: 1-800-ADC-2670
Voice: 1-516-273-9600
Fax: 1-516-273-9659
Email: adcprod@aol.com
http://www.mastermall.com/adc
NEW YORK • LONDON • TAIPEI • TOKYO

AMERICAN DIAGNOSTIC CORPORATION

3. **Predicate Device Information:**

Graham-Field Healthcare Products Electronic Stethoscope
Model: Labtron Electromax
510(k) number: K961857

4. **Device Description:**

ADC #656BK Electronic Scope

5. **Intended Use:**

For listening and amplification of sounds associated with the heart, arteries, veins and other internal organs, using the principles of electronic amplification to intensify the acoustical sounds of the device.

6. **Comparison of Predicate Devices:**

Basic design is identical in both operation and functionality to the Graham-Field Healthcare Products, Labtron Electronmax (510(k) K961857). The main amplifying chestpiece is identical to the Graham-Field Healthcare Products stethoscope in design, function and performance. The headset assembly is identical to one used on numerous other ADC stethoscopes (510(k) 935544).

55 Commerce Drive
Hauppauge, NY 11788
Customer Service: 1-800-ADC-2670
Voice: 1-516-273-9600
Fax: 1-516-273-9659
Email: adcprod@aol.com
http://www.mastermall.com/adc
NEW YORK • LONDON • TAIPEI • TOKYO

AMERICAN DIAGNOSTIC CORPORATION

7. **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as follows :**

Testing information substantiating safety and effectiveness of the ADC 656BK Electronic Scope in the intended environment of use is supported by testing conducted in accordance with FDA's guidelines "Reviewer Guidance for PMN Submission". DCRND outlining electrical, mechanical and environmental Performance standards.

8. **Discussion of Clinical Test Performed:**

Non- Applicable

9. **Conclusion:**

Based upon the previous information, the ADC 656BK Electronic Scope is substantially equivalent to the Graham-Field Healthcare Products Labtron Electromax Electronic Stethoscope. Both safety and effectiveness have been established.

55 Commerce Drive
Hauppauge, NY 11788
Customer Service: 1-800-ADC-2670
Voice: 1-516-273-9600
Fax: 1-516-273-9659
Email: adcprod@aol.com
http://www.mastermall.com/adc
NEW YORK • LONDON • TAIPEI • TOKYO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 01 2001

Mr. Marc Blitstein
President/CEO
American Diagnostic Corporation
55 Commerce Drive
Hauppauge, NY 11788

Re: K012304
Trade Name: ADC 656 Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: August 13, 2001
Received: August 21, 2001

Dear Mr. Blitstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

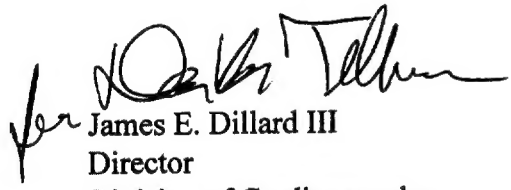
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AMERICAN DIAGNOSTIC CORPORATION

NOV 0 1 2001

K012304

August 13, 2001

Indications for Use

Device Name: ADC 656 Electronic Stethoscope
510k: K012304

American Diagnostic Corporation's number 656 Electronic Stethoscope indications for use as an electronic stethoscope which will electronically amplfy sounds associated with the heart, arteries, veins and other internal organs. American Diagnostic intends to provide this device for use by healthcare providers and not for use by the general public.

Sincerely
AMERICAN DIGNOSTIC CORP.

Marc Blitstein
President/CEO

Division of Cardiovascular & Respiratory Devices
510(k) Number K012304

Prescription Use ✓
(Per 21 CFR 801.109)

55 Commerce Drive
Hauppauge, NY 11788
Customer Service: 1-800-ADC-2670
Voice: 1-516-273-9600
Fax: 1-516-273-9659
Email: adcprod@aol.com
http://www.mastermall.com/adc
NEW YORK • LONDON • TAIPEI • TOKYO